REMARKS

The Office Action mailed on November 20, 2006 has been carefully considered by Applicant.

By the present amendment, the claims in the present application have been amended to more particularly point out and distinctly claim the subject matter believed allowable over the applied references and to remove any of the Examiner's objections.

In the Office Action, claims 24, 25, 35 and 58 have been rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant regards as the invention. Claims 1-37, 39, and 43-58 have been rejected under 35 U.S.C. §102(b) as being anticipated by Cairnes, U.S. Patent No. 6,139,494 (hereinafter Cairnes '494). Claims 33-45 have been rejected under 35 U.S.C. §102(b) as being anticipated by Walker et al., U.S. Patent No. 6,302,844 (hereinafter Walker '844). Claims 38 and 40-42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Cairnes '494 in view of Walker et al. '844.

Claims 1-10

Claim 1, as amended, is directed to a patient physiological monitoring assembly that comprises a plurality of sensors for collecting physiologic data and a controller for receiving the physiologic data and a logic adaptive to cross-reference the physiologic data with a first logic rule set, the first logic rule set including a plurality of logic rules to generate a first plurality of diagnostic interpretations. As amended, the logic is further adapted to select a second logic rule set from which the controller generates a second plurality of diagnostic interpretations. As described in the specification, the two rule sets allow the monitoring assembly to generate two diagnostic interpretations, which may or may not be the same.

Cairnes '494 fails to teach an apparatus that applies a first logic rule set to physiological data to produce a first diagnostic interpretation of the physiological data and applies a second logic rule set to the physiological data to produce a second diagnostic interpretation of the physiological data. Cairnes '494 fails to teach the use of multiple logic rule sets to produce potentially differing diagnosis based upon different rule sets. As described above, the present invention of claim 1 provides a "second opinion" diagnostic

interpretation of the patient physiologic data whereas Cairnes '494 applies a single logic rule set to produce a single recommended treatment.

Furthermore, the controller in claim 1 uses the first and second logic rule sets to produce a first and second diagnostic interpretation that will aid a clinician in making a diagnosis of the patient's medical condition, whereas the apparatus in Cairnes '494 produces one recommended therapy that is delivered to the patient. In Cairnes '494, the recommended therapy is only sent to a clinician for review after the recommended therapy is delivered to the patient. In light of these arguments, claim 1 is believed allowable.

Claims 2-10 depend directly or indirectly from claim 1 and are therefore believed allowable for the reasons stated above, as well as the subject matter recited therein.

Specifically, amended claim 3 depends directly from claim 1 and includes the additional limitation that the first and second logic rule sets are stored in a rules database that comprises a plurality of logic rule sets. While Cairnes '494 discloses the use of a database for storing a plurality of logic rules, Cairnes '494 does not disclose the grouping of the logic rules into a plurality of rule sets, the pluralities of rules to be applied as a rule set to produce a diagnostic interpretation. Cairnes '494 further does not disclose the application of a first rule set to produce a first diagnostic interpretation based on the physiologic data and the application of a second rule set to produce an independent second diagnostic interpretation based on the physiologic data. Therefore, claim 3 is believed allowable for the reasons stated above as well as the subject matter recited therein.

Claims 11-20 and 59

Presently amended claim 11 recites a method for providing a diagnostic aid to a clinician monitoring the medical condition of a patient. The method includes the step of storing a plurality of rule-based algorithms that can generate different diagnostic interpretations. Data relating to the patient is acquired from at least one sensor. The acquired data is then used to determine at least one rule-based algorithm of the plurality to be applied to the acquired data. The at least one of the plurality of rule-based algorithms is applied to the acquired data and a diagnostic interpretation is generated based upon the application of the at least one rule-based algorithm to the acquired data. Finally, the diagnostic interpretation is displayed to the clinician.

The method of claim 11 is not anticipated by Cairnes '494 because the method is directed to providing a diagnostic aid to a clinician, rather than providing a recommended treatment directly to a patient. In Cairnes '494 the recommended treatment is sent to the patient directly, and only sent to a clinician for oversight, whereas in the presently claimed method the diagnostic interpretation is sent to the clinician where the clinician may use the generated diagnostic interpretation in formulating the clinician's own opinion of the medical condition of the patient.

Furthermore, the method of claim 11 utilizes the acquired patient data in making a determination of the rule-based algorithm to apply to the patient data. The Examiner has cited column 5, lines 36-50 and column 15, lines 15-27 of Cairnes '494 as teaching this step of the method, yet these specific references contain no specific disclosure of utilizing acquired patient data to determine the selection of a rule-based algorithm to apply. More specifically, even if the Examiner is implying that the patient's medical history data necessarily influences the determination of the clinical management rules to be used, the patient medical history data is not acquired from a sensor as stated in presently amended claim 11. Therefore, presently amended claim 11 is believed allowable over Cairnes '494. Such action is respectfully requested.

Newly added claim 59 is dependant from claim 11 and further comprises the step of applying a second additional rule-based algorithm to the acquired data; generating a second diagnostic interpretation based on the application of the at least one additional rule-based algorithm, and displaying the second diagnostic interpretation to the clinician. Cairnes '494 does not teach the generation and display of a first diagnostic interpretation based on a first rule based algorithm and a second diagnostic interpretation based on a second rule-based algorithm. Cairnes '494 only teaches using a single algorithm to designate a recommended set of therapies. Therefore, Cairnes '494 does not provide the diagnostic redundancy that improves the quality of a final diagnostic determination as provided for by the invention claimed in claim 59. Claim 59 is believed allowable for the subject matter recited therein as well as the reasons stated above.

Claims 12-14, 16, 17, 19, and 20 all depend directly or indirectly from independent claim 11 which is believed allowable. As such, these claims are believe allowable for the reasons stated above, as well as the subject matter recited herein.

Claims 19 and 20 have been objected to as the original claim language made it difficult to precisely determine the scope of the claims. Claims 19 and 20 have been amended to more distinctly claim and point out that which the Applicant regards as the invention. Removal of the objections is respectfully requested.

Claims 21-28

Claim 21 recites a method for diagnosing the medical condition of a patient by acquiring patient data, applying a rule set comprising a plurality of rule-based algorithms, generating a plurality of diagnostic interpretations of the patient data based on the application of the plurality of algorithms and evaluating the plurality of diagnostic interpretations to determine the medical condition of the patient and selecting a diagnosis of the medical condition of the patient from the plurality of diagnostic interpretations. Claim 21 has been amended to add the elements of evaluating the plurality of diagnostic interpretations to determine the medical condition of the patient and selecting a diagnosis of the medical condition of the patient from the plurality of diagnostic interpretations. These two elements are not taught by the cited Cairnes '494 reference. The system taught in Cairnes '494 accepts medical data, analyzes this data according to rules, generates patient information and uses this information to assign at least one therapy responsive to the patient information. Cairnes '494 does not teach of the formulation of different diagnostic interpretations and the evaluation of these different diagnostic interpretations to select a diagnosis of the patient's medical condition. Claim 21 is believed allowable for the aforementioned reasons.

Claims 22 and 24-28 depend directly or indirectly from presently amended claim 21 and as such are believed allowable for the reasons stated above as well as the subject matter recited therein.

Specifically, presently amended claim 28 claims generating a certainty score for each of the diagnostic interpretations. The generation of a certainty score for each of the diagnostic interpretations aids the clinician in evaluating the diagnostic interpretations and to select the appropriate diagnosis of the patient. The Examiner has cited column 9, lines 1-8 of

the Cairnes '494 reference as teaching the generation of a certainty score; however, at most the cited reference discloses the conversion of raw medical data into a patient information summary including text, numerical or graphical representations. A summary of raw physiological data is not a certainty score and no disclosure of a certainty score generation, nor the added benefit of the generation of a certainty score is disclosed. Therefore, claim 28 is believed to be independently allowable for the reasons cited above, as well as the subject matter as recited therein.

Claim 24 and 25 have been rejected under 35 U.S.C. §112 for reciting the limitation "inputting data relating to the subject" for which there is insufficient antecedent basis. This limitation as been amended to state "acquiring patient data" which finds antecedent basis in presently amended claim 21, upon which both claims depend. Removal of these rejections are respectfully requested.

Claims 29, 30, and 60-62

Currently amended claim 29 recites a method comprising storing a plurality of rule-based algorithms; acquiring physiological data relating to more than one patient characteristic; based on the patient characteristics, selecting a plurality of the stored rule-based algorithms; applying the selected rule-based algorithms to the acquired physiological data; and generating a plurality of diagnostic interpretations. Presently amended claim 29 includes the element of selecting a plurality of the stored rule-based algorithms based on the patient characteristics. Therefore, in the claimed invention of claim 29 the rule-based algorithms that are to be applied are not selected until after at least some of the physiological data has been acquired and therefore the rule-based algorithms can be selected to properly analyze the acquired physiological data. The '494 patent does not teach of analyzing the acquired data to determine the rule-based algorithms to be used in the analysis of that data.

Cairnes '494 also fails to disclose the selection of rule-based algorithms from a stored plurality of rule-based algorithms. Rather, the '494 patent merely teaches of the application of rule-based algorithms to the acquired data. While the Examiner has cited Cairnes '494 column 15, lines 5-27 as teaching the determination of which rule based algorithms to apply, the cited reference does not do so. While column 15, lines 11-18 teaches an example of applying lipid management rules to five major factors, no teaching of the selection of the

rules in relation to acquired physiological data is made. Furthermore, the lipid management rules are applied to factors that are not physiological data acquired by a sensor attached to the patient. Therefore, Cairnes '494 does not teach of the invention claimed in claim 29 and claim 29 is thus believe allowable.

Claims 30 and 60-62 depend directly or indirectly from presently amended claim 29 and are thus believed allowable for the reasons stated above as well as the subject matter recited therein.

Specifically, newly presented claim 60 includes the elements of displaying the plurality of diagnostic interpretations to a clinician; prompting the clinician for a selection of one of the plurality of diagnostic interpretations; and receiving a selection for the clinician of one of the plurality of diagnostic interpretations. Cairnes '494 does not teach of the necessary involvement of the clinician in the diagnosis and/or treatment of the patient for practice of the claimed method. In Cairnes '494 the clinician serves a merely supervisory role providing oversight to the automated system. Referring to column 15, lines 18-27, the system "electronically sends a summarized report of the test results in simple language to the patient" and "the health providers review the reports to evaluate the patient's drug therapy status." "If necessary a health provider may modify the drug therapy recommended by the support results and transmit the changes with an explanation [to the patient]." The method of claim 60 serves as a tool for a clinician to more quickly and accurately perform a diagnosis of a patient's medical condition and therefore leaves the ultimate decision making authority to the clinician for diagnosing the patient rather than the automated system of Cairnes '494. Claim 60 receives a selection from the clinician of one of the plurality of diagnostic interpretations, therefore necessarily involving the clinician in the diagnosis. As such, newly presented claim 60 is believed allowable for the reasons stated above as well as the subject matter recited therein.

Newly presented claim 62 is dependent upon claim 60 and further comprises the elements of selecting a new plurality of rule-based algorithms based upon the diagnostic interpretation selected by the clinician and applying the new plurality of algorithms to the physiological data to produce a new diagnostic interpretation. Newly presented claim 62 adds a new layer to the analysis performed in claim 60 by instituting a second round of

analysis of the physiological data resulting in a new plurality of rule-based algorithms based upon the results of the first diagnostic interpretations. Cairnes '494 produces the end result of a single recommended therapy and delivers this to the patient. Cairnes '494 does not provide the in-depth second level of analysis provided by the invention claimed in claim 62. Claim 62 provides a more detailed or specific analysis that is targeted based on the first application of rule-based algorithms to the physiological data. As such, claim 62 is believed independently allowable for the reasons stated above as well as the subject matter recited therein.

Claims 33-38

Presently amended claim 33 claims a system for using rule-based algorithms and includes the elements of a data acquisition device configured to acquire data from a patient; a controller that receives and processes the acquired data; a first logic configured to select a rule based algorithm of the data storage device to the acquired data; and a second logic configured to apply the data acquired from the patient to the selected rule-based algorithm to produce a diagnostic interpretation. Claim 33 has been rejected by the Examiner under 35 U.S.C. §102(b) both in view of Cairnes '494 and Walker et al. U.S. Patent No. 6,302, 844 (hereinafter Walker et al. '844). The presently added elements to claim 33 more distinctly define the invention claimed and distinguish the claim from the cited patent references.

In regards to the Cairnes '494 reference, the presently amended claim 33 comprises the additional element of a first logic configured to select a rule-based algorithm of the data storage device to be applied to this acquired data. This element is not taught in the Cairnes '494 patent reference.

The Examiner cited the disclosure in Cairnes '494 at column 6, lines 1-20 and column 8, lines 5-27 as teaching a logic being configured to identify a rule-based algorithm. However, the closest disclosure at column 6, lines 1-20 discloses a database that may be remotely located on a separate central database server and the closest disclosure in column 8, lines 5-27 discloses that the decision support software is able to be customized and updated on an on-going basis and that the system is easily modified with respect to the data that is captured and the decision support that it provides. The disclosure cited by the Examiner does not teach of the system itself selecting the proper rule-based algorithm to use to analyze the

acquired data. Furthermore, the Cairnes '494 reference does not teach of the acquisition of data from a patient and logic configured to select a rule-based algorithm based on this acquired data. Therefore, presently amended claim 33 is believed allowable over the Cairnes '494 reference.

The Examiner also cited the Walker et al. '844 with specific reference to column 5 lines 45-67 and column 7 lines 5-60 as teaching a logic configured to identify a rule-based algorithm based on the characteristics of a subject. However, column 5 of the Walker et al. '844 patent discloses issuing an alert in the event of a patient characteristic falling below a predetermined threshold and column 7 discloses identifying whether or not an aberration in the acquired data is pathological, and if pathological, forwarding the data to a physician. The disclosure in Walker et al. '844 does not disclose acquiring data from a patient and using a first logic configured to select a rule based algorithm to be applied to the acquired data from the data storage device. The disclosure of Walker et al. '844 is limited in that it does not disclose a two tiered analysis first to identify a rule-based algorithm to use, and then to apply the rule-based algorithm to produce a diagnostic interpretation regarding the acquired patient data. For these reasons, presently amended claim 33 is believed allowable.

Claims 35 and 38 depend directly from claim 33 which is believed allowable, claims 35 and 38 are also believed allowable for the reasons stated above as well as the subject matter cited therein.

Claim 35 has also been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter the Applicant regards as the invention. Presently amended claim 35 more distinctly claims and points out the subject matter with which the Applicant regards as the invention. As such, it is respectfully requested that the Examiner's rejection be withdrawn.

Claim 38 has also been rejected under 35 U.S.C. §103(a) as being unpatentable over Cairnes '494 in view of Walker et al. '844. Claim 38 depends directly from presently amended claim 33 which is distinguished from the cited Cairnes '494 and Walker et al. '844 references for the reasons stated above. Specifically, presently amended claim 33 includes the elements of a first logic that analyzes acquired data and selects a rule-based algorithm to

apply to the acquired data. This element is not taught by either Cairnes '494 or Walker et al. '844. Therefore, claim 38 is believed allowable.

Claims 42, 45 and 63

Newly presented claim 63 has been added to replace presently cancelled claim 39. Newly added claim 63 comprises the element of storing a plurality of rule-based algorithms at a plurality of data storage locations comprising a local data storage and at least one remote data storage, the at least one remote data storage comprising at least one data storage outside of an information network of a healthcare facility. The Examiner rejected presently cancelled claim 39 under 35 U.S.C. §102(b) with reference to both Cairnes '494 and Walker et al. '844. The references cited by the Examiner fail to teach that the rule-based algorithms are stored at a plurality of locations with at least one of those locations being remote from the medical monitor and at least one of the data storages being outside of the information network of a healthcare facility. While Cairnes '494 discloses experts in a specific medical field updating and electronically returning the clinical management rules to the personal health advisor, the '494 reference fails to teach of the use of data storage outside of an information network of a healthcare facility that is accessible by a communications network for the transfer of a rule-based algorithm. In rejecting claim 39, the Examiner cited Walker et al. '844 column 21 lines 21-26 as teaching the transferring a rule-based algorithm across a network. However, the reference cited by the Examiner does not teach of the transfer of a rule-based algorithm, rather the reference cited by the Examiner teaches of a third party accessing patient information via the internet. Therefore Walker et al. '844 fails to teach accessing and transferring a rule-based algorithm located outside of the information network of a healthcare facility via a network.

Furthermore, newly added claim 63 comprises the elements of collecting patient information and transferring at least one rule based algorithm across a communications network connecting the plurality of data storage locations with the medical monitor if the patient meets a predetermined condition. Cairnes '494 fails to teach the elements of collecting patient information and transferring at least one rule-based algorithm as Cairnes '494 fails to teach collecting patient information and using the collected patient information to control the transfer and/or selection of at least one rule-based algorithm to be used in

analyzing acquired patient data. In rejecting claim 39, the Examiner cited Walker et al. '844 column 7 lines 13-44 as teaching storing a rule-based algorithm. The reference cited by the Examiner describes "a high-level block diagram of a central server suitable for use in the patient care diagnosis delivery system." The reference cited by the Examiner only teaches of a database in a central server, rather than the plurality of data storage locations comprising a local data storage, at least one remote data storage and at least one data storage outside of a information network of a healthcare facility. As such, claim 63 is believed allowable over the references cited by the Examiner, such action is earnestly requested.

Claims 42 and 45 depend directly from independent claim 63 which is believed allowable; therefore, claims 42 and 45 are also believed allowable for the reasons stated above as well as the subject matter recited therein.

Claims 51, 64 and 65

Newly added independent claim 64 replaces presently cancelled independent claim 46. Newly added claim 64 comprises the elements of at least one data storage device comprising a plurality of rule sets, each rule set comprising at least one rule-based algorithm being written by an unrelated group; and a logic configured to apply at least one rule set to the physiological data to produce at least one diagnostic interpretation. Cairnes '494 fails to teach the application of a plurality of rule-based algorithms as a rule set as recited in newly presented claim 64. Cairnes '494 only discloses the transfer and application of a single rule-based algorithm for application to the acquired data. One of the advantages of the present invention is that multiple rule-based algorithms, which are grouped as rule sets, may be applied to the physiological data in order to produce a more accurate diagnostic interpretation as each of the rule-based algorithms may produce a diagnostic interpretation, thus presenting a clinician with a plurality of diagnostic interpretations to choose from. This distinguishes the present invention from the cited Cairnes '494 reference. As such, newly added claim 64 is believed allowable over the references cited by the Examiner.

Claim 51 has been amended to depend directly from claim 64. In originally rejecting claim 51, the Examiner cited Cairnes '494 column 5, lines 30-65 and column 6 lines 1-20 for teaching that the rule-based algorithms are transferred from a system outside of a healthcare facility's network. The cited references fail to teach the transfer of the rule-based algorithms

to the patient monitor from a system outside of a healthcare facility's network. Cairnes '494 teaches of the use of a local database 130 or a separate central database server 132. Both of these databases are databases that are within a healthcare facility's network. While the Cairnes '494 reference teaches a connection to a variety of other information sources including a specialized physician, other health providers, a pharmacy, an information services site, a clinician lab, a hospital, and a population database, Cairnes '494 does not disclose that any of these other information sources are a source of any rule sets to be transferred to the patient monitor. Therefore, claim 51 is believed to be independently allowable for the reasons stated above as well as the subject matter recited therein.

Newly added claim 65 depends directly from claim 64 and comprises the user interface being configured to facilitate the transfer of at least two rule sets; and the logic being configured to produce at least one diagnostic interpretation of each rule set applied to the physiological data. The Cairnes '494 reference fails to teach the additional elements of newly added claim 65 as newly added claim 65 comprises the transfer of at least two rule sets which are used by the logic to produce at least one diagnostic interpretation for each rule set, therefore producing at least two diagnostic interpretations. The Cairnes '494 reference fails to teach the application of multiple rule-based algorithms, let alone the application of multiple sets of rule-based algorithms.

Cairnes '494 is limited in the diagnostic interpretations that the system produces, only producing a single recommended therapy that is delivered to the patient. The recommended therapy may comprise multiple elements, such as the diet, exercise, and smoking cessation therapy disclosed at Cairnes '494 column 16, lines 7-10; however, this is presented as a single therapy as opposed to generation of multiple independent diagnostic interpretations from which the clinician can select, as claimed in claim 65. One advantage of the invention claimed in newly added claim 65 is that at least two diagnostic interpretations are produced based on analysis of the same physiological data. This provides an attending clinician with a readily available "second opinion" that can help to improve the quality and accuracy of the diagnosis that is made. Therefore, newly added claim 65 is believed independently allowable for the reasons stated above as well as the subject matter recited therein.

Claims 53-57, 66 and 67

Newly added independent claim 66 replaces presently cancelled independent claim 52 and recites acquiring data from a plurality of sensors that are coupled to a patient; selecting a first rule set comprising a first plurality of rule-based algorithms based on the acquired data; applying the first rule set to the acquired data to produce a first plurality of diagnostic interpretations; displaying the first plurality of diagnostic interpretations; and receiving a selection of one of the plurality of diagnostic interpretations. The method further comprises the elements of a second rule set comprising a second plurality of rule-based algorithms based on the selected diagnostic interpretation; applying the second rule set to the acquired data to produce a second plurality of diagnostic interpretations; and displaying the second plurality of diagnostic interpretations.

Newly presented claim 66 is believed allowable over the references cited by the Examiner as the references cited by the Examiner do not teach or disclose of selecting a rule-based algorithm based upon either the data acquired from the patient, or the selection of a diagnostic interpretation. The references cited by the Examiner merely apply existing rule-based algorithms to acquired patient data or to identify a recommended therapy (as in Cairnes' 494) or to identify a clinician that should be contacted regarding further medical treatment (as in Walker et al. '844). The references cited by the Examiner further do not produce either a first diagnostic interpretation, nor do they disclose the production of a second diagnostic interpretation that is based in part upon the results of the first diagnostic interpretation.

Finally, the references cited by the Examiner fail to teach or disclose the application of a second rule set that is used to produce a second plurality of diagnostic interpretations. The additional analysis and production of additional diagnostic interpretations presents an advantage over the cited references in that the second plurality of diagnostic interpretations are more focused and specific based upon the results of the first plurality of diagnostic interpretations. Therefore, newly added claim 66 is believed allowable over the references cited by the Examiner.

Claims 52, 56, 57 and 67 depend directly from newly added independent claim 66. As such, these claims are also believed allowable for the reasons stated above, as well as the subjected matter recited therein.

Specifically, claim 67 comprises the element of displaying a certainty score for each diagnostic interpretation of the plurality of diagnostic interpretations. The references cited by the Examiner do not teach of the generation of a certainty score for each of the diagnostic interpretations of the plurality of diagnostic interpretations. The Examiner has previously cited column 9 lines 1-8 of the Cairnes '494 patent as teaching the generation and displaying of a certainty score; however the cited reference fails to teach of the generation of a certainty score as the data information conversion function 127 converts raw sign and symptom provided by a patient into a usable information such as summarized text, and numerical or graphical representations. This is not the same as a certainty score with regards to a diagnostic interpretation that reflects a statistical confidence level of the diagnostic interpretation based upon the patient data analyzed by the rule-based algorithm. As such, claim 67 is believed independently allowable for the reasons stated above as well as the subject matter recited therein.

Conclusion

The present application is thus believed in condition for allowance with claims 1-3, 5-14, 16, 17, 19-22, 24-30, 33, 35, 38, 42, 45, 51, 53, 56, 57 and 59-67. Such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By 
Joseph D. Kuborn
Reg. No. 40,689

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
Telephone: (414) 271-7590
Facsimile: (414) 271-5770